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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/594,507 | 09/28/2006 | Haruo Sugiyama | 296846US0PCT | 1680 |

22850 7590 04/08/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
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| EXAMINER | |
|---|---|
| RUSSEL, JEFFREY E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 04/08/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/594,507 | SUGIYAMA, HARUO | |
| | Examiner | Art Unit | |
| | Jeffrey E. Russel | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26-30* is/are allowed.

6)☒ Claim(s) *21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20081229*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election without traverse of the invention of Group I, claims 1-3 and 11-13, and the species peptide of SEQ ID NO:9 in the reply filed on August 4, 2008 is acknowledged.

Claim 30, i.e. limited to the elected species peptide of SEQ ID NO:9, has been examined and determined to be novel and unobvious over the prior art of record. Accordingly, the election of species requirement set forth in the Office action mailed July 2, 2008 is withdrawn, and search and examination has been extended to all of the species encompassed by the pending claims.

2. The abstract of the disclosure is objected to because of the presence of the legal terminology "said". Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: At page 7, line 25, "binding" is misspelled. Appropriate correction is required.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

5. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 03/037060. The WO Patent Application '060 teaches peptides identified as SEQ ID NOS:244, 60, and 166 (see pages 94 (Table II), 98 (Table VII), and 118 (Table XXXIII)) which

are the same as Applicant's peptides identified as SEQ ID NOS:8, 2, and 9, respectively. The WO Patent Application '060 also teaches a vaccination composition comprising an immunogenic fragment of WT-1 corresponding to residues 2-281. See page 175, lines 4-6, and Example 35 in general. The amino acid sequence of this fragment is taught at page 173, lines 27-29 (identified as SEQ ID NO:461), and comprises Applicant's SEQ ID NO:8 and SEQ ID NO:9 (see positions 151-159 and 184-192 of SEQ ID NO:461). The WO Patent Application '060 teaches the use of these peptides in patients, including human patients and WT1-positive patients, to treat or prevent diseases such as leukemia or cancer. See, e.g., page 2, lines 11-12, 17-20, and 27-29; page 4, lines 14-26; page 15, lines 22-29; and page 17, lines 8-10. The WO Patent Application '060 does not teach using immunogenic fragments of WT-1, including the fragment comprising residues 2-281, or SEQ ID NOS:244, 60, and 166, to treat or prevent diseases such as leukemia or cancer in patients who are HLA-A26 positive. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the immunogenic fragments of WT-1 taught by the WO Patent Application '060, including the fragment comprising residues 2-281, and SEQ ID NOS:244, 60, and 166, to treat or prevent diseases such as leukemia or cancer as taught by the WO Patent Application '060, in patients who are HLA-A26 positive, because the WO Patent Application '060 does not limit its treatments to patients expressing any particular HLA type (see, e.g., page 16, line 28 - page 17, line 1), and because it is desirable to treat or prevent diseases such as leukemia or cancer in all patients regardless of HLA type. The results recited in instant claims 21-25 are expected, rather than unexpected, in view of the disclosure of the WO Patent Application '060.

6. Applicant's arguments filed December 29, 2008 have been fully considered but they are not persuasive.

Applicant's response did not include any amendments or arguments directed to the objection to the Abstract or to the objection to the misspelling at page 7, line 25, of the specification.

The WO Patent Application 03/037060 continues to be applied, against new claims 21-25, under 35 U.S.C. 103(a). Note that in contrast to claims 21-25, claims 26-30 require a particular result that is neither inherent nor obvious in view of the WO Patent Application '060, namely that the peptides form a complex with HLA-A26 positive peripheral blood mononuclear cells and that a CTL recognizing that complex be induced. The rejected claims do not require any effect other than the one disclosed by the WO Patent Application '060, namely that cancer is treated or prevented, and do not require induction of CTLs in an HLA-A26 restricted manner. Note also that actual reduction to practice is not a pre-requisite for prior art rejections under 35 U.S.C. 102(b) or 103.

The anticipation rejection over Gaiger et al (U.S. Patent Application Publication 2003/0082194) set forth in the previous Office action is overcome in view of Applicant's amendments to the claims. Gaiger et al is essentially duplicative of the WO Patent Application '060, especially with respect to new claims 21-25, and accordingly Gaiger et al is not currently applied against the new claims.

7. Claims 26-30 are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
April 6, 2009